

⑫ **EUROPEAN PATENT APPLICATION**

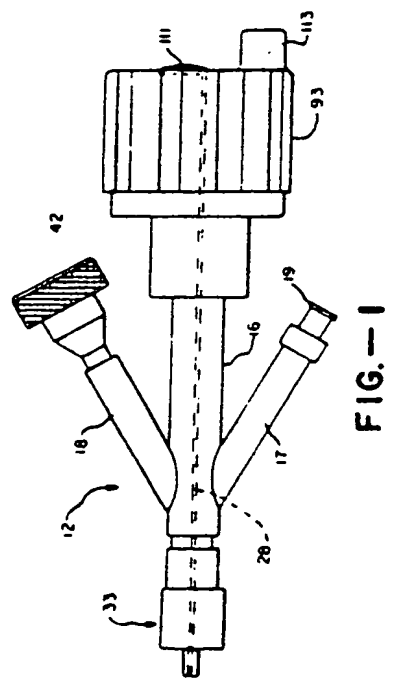
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⑤④ **Steerable dilatation catheter with rotation limiting device.**

⑤⑦ A steerable dilatation catheter assembly having an adapter with at least one arm (12). A guide wire having proximal and distal ends is provided with the proximal ends (28) extending through the adapter. A flexible tubular member has one end secured to the adapter and extends over the guide wire and has a balloon carried by a distal portion thereof. The distal extremity of the balloon is bonded to the guide wire to form a liquid-tight seal between the guide wire and the balloon. A flexible tip is secured to the guide wire. A rotation limiter (93) secured to the guide wire and carried by the arm for rotating the guide wire through a number of turns less than a predetermined number of turns.



EP 0 213 751 A1

## STEERABLE DILATATION CATHETER WITH ROTATION LIMITING DEVICE

This application relates to a steerable dilatation catheter assembly with a rotation limiting device and more particularly, to a low profile steerable dilatation catheter with a rotation limiting device.

In U. S. Letters Patent No. 4,582,181 there is disclosed a steerable dilatation catheter. Difficulties have been encountered with this catheter in that surgeons using the same have rotated the guide wire to such an extent that the balloon has been twisted making it difficult to inflate. There is therefore a need for a new and improved steerable dilatation catheter which will overcome this difficulty.

The present invention provides a steerable dilatation catheter with a rotation limiting device.

In general, the low profile steerable dilatation catheter assembly is comprised of a guide wire having proximal and distal ends. An adapter is provided with at least one arm having the guide wire extending therethrough. An elongate flexible tubular member extends over the guide wire from the adapter to a region near the distal extremity of the guide wire. A flexible tip is carried by the guide wire. The tubular member carries an inflatable balloon that has its distal extremity secured to the core wire so as to provide a liquid-tight seal. A rotation limiting device is carried by the arm of the adapter. The rotating limiting device includes a rotatable member and means securing the guide wire to the rotatable member. Means is also provided which engages the rotatable member for preventing rotation of the rotatable member for more than a predetermined number of turns.

The present invention is further described by way of example only with reference to the accompanying drawings, in which;

Figure 1 is a partial side elevational view of a catheter assembly with a rotation limiting device incorporating the present invention.

Figure 2 is a cross sectional view of the rotation limiting device shown in Figure 1.

Figure 3 is an exploded view of the rotation limiting device shown in Figure 2.

More particularly, the steerable dilatation catheter assembly with a rotation limiting device as shown in Figures 1-3 consists of an adapter 12. A rotation limiting device 92 is mounted on the central arm 16 of the adapter 12. The rotation limiting device 92 includes a rotatable member 93 which is in the form of a cylindrical cap which is provided with a side wall 94 and a top or end wall 96. The side wall 94 is provided with circumferentially spaced outwardly facing recesses 97 extending longitudinally thereof which facilitate gripping of the outer surface 94 by hand during operation as

hereinafter described. The top wall 96 is provided with a centrally disposed hole 98 which opens into a recess 99. The hole 98 opens into a centrally disposed bore 101 which extends through a centrally disposed cylindrical stem 102 concentric with the side wall 94. A cylindrical recess 103 is provided within the rotatable member 93.

The cap or housing which is formed by the rotatable member 93 is rotatably mounted upon an adapter 104 which is adapted to be mounted on the central arm 16 by suitable means such as an adhesive fit. The adapter 104 is provided with a truncated conical surface 106 which facilitates this mounting. The adapter is provided with a centrally disposed bore 107 which is adapted to receive the distal extremity of the stem 102. The adapter 104 is provided with an annular recess 108 which is adapted to carry suitable sealing means such as an O-ring 109. The O-ring 109 thus serves to form a liquid-tight seal between the adapter 104 and the stem 102 of the housing 93.

The guide wire 28 is adapted to extend through the bore 101 and to be inserted in the hole 98 and bent into the recess 99 after which suitable sealing means is provided such as an epoxy 111 which secures the end of the guide wire 28 in the recess 99. An outwardly extending protrusion 113 is provided on the top wall 96 and extends outwardly therefrom. It is adapted to be engaged by a finger of a hand to facilitate rotation of the rotatable member 93. The proximal extremity of the guide wire 28, since it is secured to the rotatable member, will be rotated with the rotatable member.

Means is provided in the rotation limiting device for limiting the rotation to no more than a predetermined number of turns as, for example, four complete turns or revolutions. This means consists of a plurality of discs 116 which are disposed within the recess 103 as, for example, the three discs shown in Figure 2. The discs 116 can be substantially identical. Each of the discs 116 is provided with a central bore 117 and a arcuate recess 118 which is generally concentric with the bore 117. The arcuate recess 118 extends through substantially 360° except for a small web 119. Each disc has a downwardly extending cylindrical protrusion 121 which is adapted to seat in and travel in the arcuate recess 118 provided in the disc there below. The protrusion 121 of the lowermost disc is adapted to seat in an arcuate recess 123 provided in the adapter 104. The recess 123 is similar to the recesses 118 and extends through substantially 360° except for a small web 124. The rotatable member 93 is provided with a downwar-

dly extending protrusion 125 extending downwardly from the top wall 96 and which is adapted to seat in the arcuate recess 118 of the uppermost disc 116.

In assembling the rotation limiting device, the discs are inserted into the housing-like rotatable member 93 so that the uppermost disc has the protrusion 125 in its recess 118 and so that the protrusions 121 provided in the discs are disposed in the recesses 118 of the discs below. A retainer 126 is provided for retaining the adapter 104 within the lower extremity of the housing-like rotatable member 93 and is provided with a central opening 127 and an upstanding outer rim 128. The retainer 126 is adapted to engage but rotate freely with respect to the shoulder 129 of the adapter 104 and to have the rim 128 bonded to the outer lower extremity of the housing-like rotatable member 93 by suitable means such as adhesive. When assembled in this manner, the various parts of the rotation device are held together in a unitary assembly while still permitting rotation of the housing 93 relative to the adapter 104 through a predetermined number of revolutions as, for example, approximately 4. The number of revolutions is determined by the number of discs and the number of arcuate slots which are provided. As can be seen there are three slots 118 provided in the three discs 116 and another arcuate slot 123 is provided in the adapter 104.

Thus it can be seen that there has been provided a catheter assembly with a rotation limiting device which has an attractive appearance which is relatively simple to fabricate and assemble. It also provides for the maximum desired number of rotations for the guide wire.

It is apparent from the foregoing that there has been provided a low profile steerable dilatation catheter of the type which limits twisting movement of the balloon while at the same time providing sufficient torsional rigidity so that there is at least 360° rotation of the tip of the dilatation catheter and therefore it does not detract from the capabilities of the dilatation catheter. The additional torsional rigidity required in the catheter assembly to obtain the 360° rotation of the tip of the catheter

assembly with no more than two turns of the torque knob can be readily accomplished. The dilatation catheter is also of the type which can be readily manufactured and assembled.

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## Claims

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1. A rotation limiting device comprising a rotatable member, means adapted to secure the guide wire to the rotatable member, and means including a plurality of superposed discs engaging the rotatable member for prevention of rotation of the rotatable member for more than a predetermined number of times, each of said discs including cooperative protrusion and recess means.

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2. A rotation limiting device for use with a steerable dilatation catheter comprising an adapter with at least one arm, a guide wire having proximal and distal ends with the proximal end extending through the adapter and extending over the guide wire and having a balloon carried by the distal portion thereof, the balloon having a distal extremity which is bonded to the guide wire to form a liquid-tight seal between the guide wire and the balloon and a flexible tip secured to the guide wire, wherein the rotation limiting device comprises a rotatable member, means adapted to secure the guide wire to the rotatable member, and means including a plurality of superposed discs engaging the rotatable member for prevention of rotation of the rotatable member for more than a predetermined number of times, each of said discs including cooperative protrusion and recess means as claimed in claim 1.

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3. A device as claimed in claim 1 or claim 2 wherein said rotatable member is in the form of a housing having a cylindrical recess therein and wherein said discs may be disposed in said cylindrical recess.

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4. A device as claimed in claim 3 further comprising an adapter wherein the housing and the adapter each are provided with a cooperative means to cooperate with the discs.

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5. A device as claimed in claim 4 wherein each disc is provided with a recess extending through substantially 360° and a protrusion which is adapted to seat in the recess of another disc.

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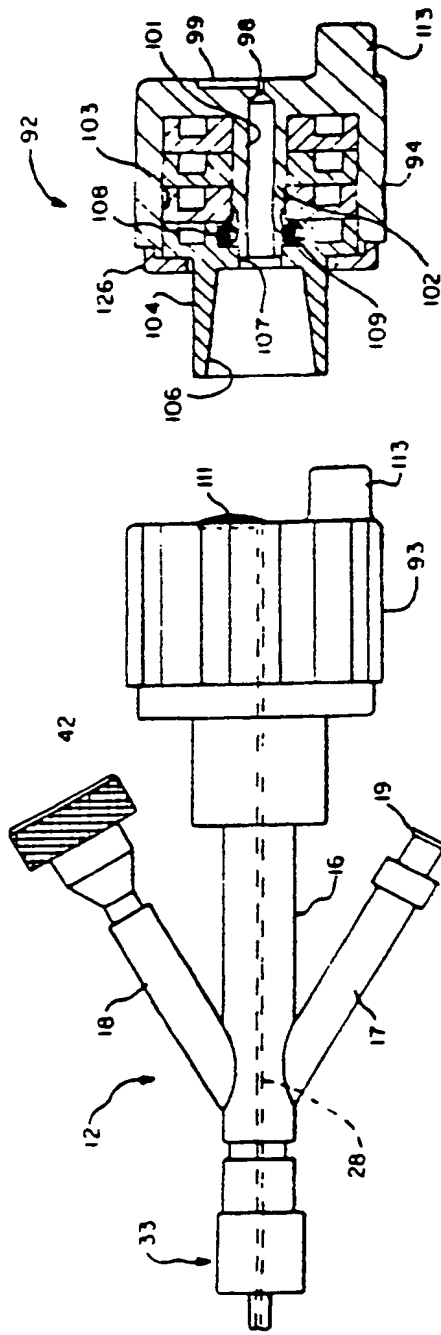


FIG. 1

FIG. 2

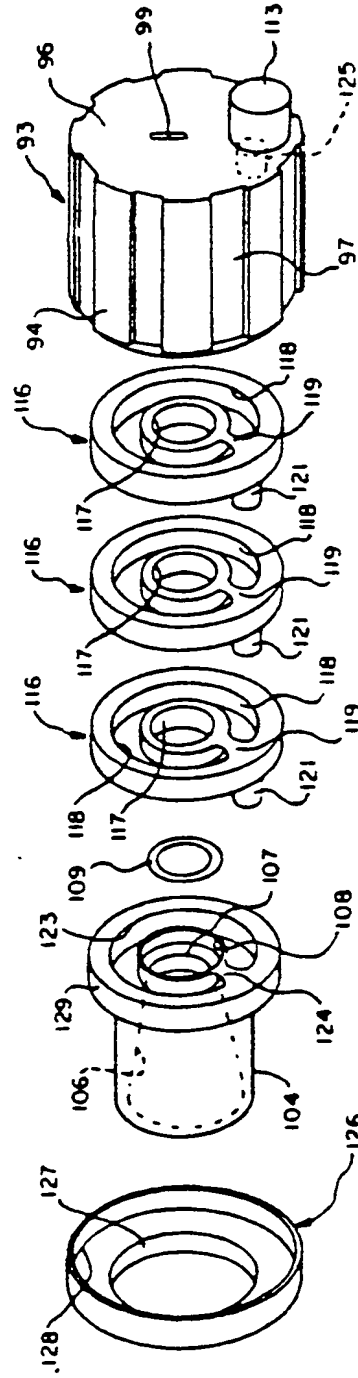


FIG. 3



DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.)
X	FR-A- 965 022 (JULLIEN) * Page 3, lines 39-51; figures 1-4 *	1	A 61 M 29/02 A 61 M 25/00 G 05 G 5/04
A	---	2	
A	US-A-3 452 740 (MULLER) * Description; figures *	2	
A	---		
A	US-A-2 688 882 (ALEXY) * Column 5, lines 10-19; figure 6 *	1, 4, 5	
P, A	---		
P, A	EP-A-0 165 727 (ADVANCED CARDIOVASCULAR SYSTEMS) * Abstract; figures *	2, 3	
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The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 27-11-1986	Examiner VANRUNXT J. M. A.
<b>CATEGORY OF CITED DOCUMENTS</b>			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

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